THIS OPINION WAS NOT WRITTEN FOR PUBLICATION

The opinion in support of the decision being entered today (1) was not written for publication in a law journal and (2) is not binding precedent of the Board.

Paper No. 36

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte RAYMOND COOPER, ANN C. HORAN,
MAHESH G. PATEL and IMBI TRUUMEES

Appeal No. 94-1146
Application 07/746,050[1]

ON BRIEF

Before CAROFF, WILLIAM F. SMITH, and GRON, Administrative Patent Judges

GRON, Administrative Patent Judge.

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[1] Application for patent filed August 12, 1991. According to applicants, this application is a continuation of Application 07/590,570, filed September 28, 1990, now abandoned; which is a continuation of Application 07/227,964, filed August 3, 1988, now abandoned.

DECISION ON APPEAL UNDER 35 U.S.C. § 134

This is an appeal from an examiner's rejections of Claims 1-12, all claims pending in this application.

1. The claimed subject matter

Claim 1 is representative of the claimed macrolactam monosaccharide antimicrobial compounds and is reproduced in the attached Appendix. All claims stand or fall together (Brief on Appeal, p. 4).

The claims are directed to macrolactam monosaccharide antimicrobial compounds in substantially pure form, their pharmaceutically acceptable salts, pharmaceutical compositions comprising the pure compounds or their salts, and methods for treating a bacterial infection in a host comprising administering the compounds to the infected host. "The compounds are
isolated from an antimicrobial complex 510 which is produced in fermentation under controlled conditions using a biologically pure culture of the microorganism, Actinomadura fulva subsp. uruguayensis SCC 1778, ATCC 53713" (Specification (Spec.), p. 1, introductory paragraph). The microorganism was

isolated from soil collected in Uruguay (Spec., p. 3, last paragraph).

2. The rejections

A. Claims 1-12 stand rejected under 35 U.S.C. § 103 as being unpatentable in view of antibiotic AB-85 disclosed in Japanese Patent Publication 59-18035, published April 25, 1984.

B. Claims 1-12 stand provisionally rejected for obviousness-type double patenting of Claims 1-9 of commonly assigned copending Application 07/747,456.

C. Claims 1-12 stand provisionally rejected for obviousness-type double patenting of Claims 1-9 and 11 of commonly assigned Application 07/746,059.

3. Discussion

A. Obviousness under Section 103

The examiner has the initial burden of making out a case for obviousness under 35 U.S.C. § 103. Here, the examiner's case for obviousness is supported by the following arguments (Examiner's Answer, pp. 3-4):

> The Japanese patent discloses an antibiotic having molecular formula $C_{25}H_{28}N_2O_5$. Appellants on page 13 of the specification state that the macrolactam monosaccharide of formal [sic, formula] 2 and having the molecular formula as given, is disclosed by the

> Japanese patent. The only difference between known compound and the claimed compound is at the 9, 5 or 13 positions, i.e [sic] the known compound contains ethyl groups at the said positions while the claimed compound contains at least one methyl group at the said positions. Since methyl is a next lower homologue of ethyl, it would have been obvious to a person having ordinary skill in the art at the time of the instant invention to substitute methyl group for ethyl on the compound of formula 2 with an expected result. The instant compounds, compositions and methods are deemed obvious over the Japanese patent.

The two-part test for holding that a claimed compound would have been obvious under Section 103 over the disclosure of a structurally similar compound in the prior art is set out in

In re Payne, 606 F.2d 303, 314-15, 203 USPQ 245, 254-255 (CCPA 1979). First, we must ask whether the undisclosed structure of the AB-85 antibiotic described by Japan would have been understood by persons having ordinary skill in the art to be so similar to formula 1 of appellants' Claim 1 that they reasonably would have been led to make and use the compounds of formula 1 of Claim 1 as an antibiotic with reasonable expectation of success. Id. at 313, 203 USPQ at 254. Second, we must ask whether the prior art would have enabled persons skilled in the art to make and use the claimed compounds, i.e., would it have placed the claimed compounds in the

possession of the public. In re Payne, 606 F.2d at 314-15, 203 USPQ at 255. On considering the second part of the two-part test, we find that the examiner has not supported his allegation that the claimed antibiotic compounds would have been obvious with evidence sufficient to justify a conclusion that the prior art would have enabled one skilled in the art to make and use appellants' antibiotic compounds without appellants' disclosure.

In his declaration filed March 26, 1992 (Declaration of Min Chu (Chu), Paper No. 26), Chu declares (Chu, pp. 2-3):

> THAT, the structural formula of the antibiotic AB-85 . . . of the Japanese patent . . . [has] the formula 2 on page 15 of the US Patent Application Serial No. 07/747,456, filed 08/12/91 . . .[; and]
>
> THAT, based on information and belief and my expertise in synthetic organic chemistry, I am aware of no synthetic method as of August 3, 1988 of selectively activating and removing one, two or three of the CH_2 groups at C-5', C-9' and C-13' of AB-85 to form any of the aglycone of the compounds of this invention of formula 1. . .[;]
>
> THAT, based on information and belief and my expertise in synthetic organic chemistry, I am aware of no chemical method in existence as of August 3, 1988 of synthesizing the compounds of this invention except by the fermentation of Actinomadura fulva subsp uruguayensis of this invention; and

Conclusion

In summary, (1) I am aware of no synthetic

> technique to selectively activate and remove the one, two or three of the -CH_2- groups at C-5', C-9' and/or C-13' of the macrolactam aglycone of AB-85 to form the compounds of this invention and (2) there is no synthetic organic chemical method of making the compounds of this invention and (3) only by fermentation of the A. fulva subsp uruguayensis of this invention are the compounds of this invention available.

In short, Min Chu declares that he is not aware of any synthetic organic chemical method of preparing antibiotics including the macrolactam aglycone of this invention with a methyl radical at the C-5, C-9 and/or C-13 position from antibiotics including the macrolactam aglycone of AB-85 with an ethyl radical at the C-5, C-9 and/or C-13 position.

Faced with Chu's declaration, the examiner responded as follows (Examiner's Answer, pp. 5-6):

> . . . [T]he Declaration by Dr. Min Chu stating that Dr. Min Chu is not aware of any synthetic technique to selectively activate and remove the one, two, or three of the -CH_2- groups at the 5, 9 and 10-13 [sic, 13] position of the compound disclosed by the Japanese patent, [the] same Declaration . . . [has] not been found persuasive because the removal of the methyl group from the reference's compound can be not selective but random resulting in a mixture of compounds being formed which are subsequently separated.

However, Chu also said that he was "aware of no chemical method in existence as of August 3, 1988 of synthesizing the compounds of this invention except by the fermentation of

Actinomadura fulva subsp uruguayenis of this invention" (Chu, p. 3; emphasis added). While Chu's declaration of unobviousness is itself supported by no more evidence than is the examiner's allegation of obviousness, it is the examiner who has the initial burden to sustain his case. In our view, the examiner's case of obviousness under 35 U.S.C. § 103 in view of the teaching of Japan 59-18035 is based on pure speculation. Whether or not the motivation to synthesize organic compounds is apparent from the prior art applied against the claims in this case or debatable, the examiner must also make the inquiries necessary to prima facie establish that it would have been within the ordinary skill in the art to synthesize the compounds sought without undue experimentation, e.g., determine the unpredictability, level of skill, and suitability of conventional methodology in the art. The examiner has discussed none of the factors relevant to the outcome-determinative issue in this case. In short, the examiner appears to have rested his case of obviousness on recognizing some motivation to synthesize the claimed compounds. We repeat, standing alone motivation to synthesize structurally similar compounds is not enough to sustain a case of obviousness under

35 U.S.C. § 103. The prior art must place the claimed compounds in the possession of the public. In re Payne, 606 F.2d at 314, 203 USPQ at 255. The examiner has not satisfied his burden to establish that the prior art would have enabled persons skilled in the art to make the claimed compounds without undue experimentation. Accordingly, we reverse the examiner's rejection.

B. Obviousness-type double patenting

The provisional obviousness-type double patenting rejection of Claims 1-12 in view of the subject matter of Claims 1-9 and 11 of Application 07/746,059 is hereby reversed. The rejection is moot because the application appears to have been abandoned.

We also reverse the examiner's provisional obviousness-type double patent rejection of Claims 1-12 in view of the subject matter of Claims 1-9 of commonly assigned, copending Application 07/747,456. The examiner finds (Examiner's Answer, p. 3, first full paragraph):

> . . . [T]he conflicting claims are not identical . . . because the difference between the claimed compounds and the compound of the copending application is at the 5, 9 or 13 position i.e. the compound of the copending application has ethyl groups at the 5, 9 and 13 position [sic] while the claimed compound has a methyl group at the 5, 9 or 13 positions [sic].

> Since methyl is a next higher homologue of ethyl, the claimed compounds are obvious variants of the compound claimed in the copending application.

The examiner's finding is clearly erroneous. The difference between the claimed compounds and the compound of the copending application lies not only at the 5, 9, or 13 position of macrolactam aglycone ring of the claimed antibiotics but also in the difference between the 3-amino-3,6-dideoxymannopyranose isomer which is attached to C-6 of the macrolactam aglycone ring of the compound claimed in this application and the 3-amino-3,6-dideoxytalopyranose isomer which is attached to C-6 of the macrolactam aglycone ring of the compound claimed in the copending application. In addition to the previously stated reasons for reversing the examiner's rejection of Claims 1-12 under 35 U.S.C. § 103 in view of the teaching of Japan 59-18035, the examiner also has not established that a disclosure of one isomer would have enabled persons skilled in the art to make and use the other.

4. Conclusions

We reverse all the examiner's rejections.

REVERSED

Marc L. Caroff Administrative Patent Judge	)	
William F. Smith Administrative Patent Judge	)	BOARD OF PATENT APPEALS AND INTERFERENCES
Teddy S. Gron Administrative Patent Judge	)	

And Appeal No 94-1146
Application 07/746,050

Thomas D. Hoffman
Schering-Plough Corporation
One Giralda Farms
Madison, NJ 07940-1000